

**Application No.: 10/584,338**  
**Filing Date: January 9, 2007**

## **REMARKS**

Claims 76-84, 86, 87 and 89 are currently pending. Applicants have canceled claims 1-75, 86 and 88 without prejudice or disclaimer. Applicants reserve the right to pursue the subject matter of any or all of the canceled claims in one or more continuing applications. Applicants have amended claims 76, 81, 84 and 86 and have added claim 89. Support for each of the amendments and new claim can be found in the specification and claims as originally filed, and thus, do not constitute new matter. For example, the amendments to independent claim 76 can be found at paragraph [0098], claim 85, claim 88 and elsewhere throughout the specification as originally filed. Support for new claim 89 can be found in claim 84 and elsewhere throughout the specification as originally filed. Because each of the amendments and new claim is derived from subject matter previously examined, no new issues are raised. Accordingly, Applicants request that each of the amendments and new claim 89 be entered.

After having carefully considered the final Office Action and the comments of the Examiners during the telephonic interview of September 18, 2009, Applicants provide the following remarks to clarify why each of the rejected claims satisfy all of the statutory requirements for patentability.

### Color Drawings

The Examiner notes that the acceptance of color drawings requires a petition by Applicants to use the color drawings as acceptable drawings for printing purposes. Applicants would like to thank Examiner for the reminder but respectfully submit that Applicants do not require the use of color drawings for printing purposes.

### 35 U.S.C. §112, first paragraph

In the current Office Action, the Examiner maintains the rejection of Claims 76-87 under 35 U.S.C. §112, first paragraph, alleging that the claims are not enabled by the specification. In light of the telephonic interview of September 18, 2009, the remarks made in Applicant's response filed May 12, 2009, which are incorporated herein by reference, and the amendments set forth herein, the Examiners have agreed to withdraw this rejection.

Independent claim 76 has been amended as follows:

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76. [A] An *in vitro* method of producing human definitive endoderm cells, said method comprising:

obtaining a cell population comprising pluripotent human stem cells; and

providing said cell population with a TGF $\beta$  superfamily growth factor and a Wnt-pathway activator Wnt family member, thereby generating in said cell population definitive endoderm cells expressing at least SOX17 and HNF3 $\beta$ .

The term “*in vitro*” has been introduced to clarify that the method does not include production of definitive endoderm in humans *in vivo*. Claim 76 has also been amended to clarify that the pluripotent human cells are “pluripotent human stem cells,” which cover all types of human pluripotent stem cells including, but not limited to, those isolated from embryonic tissue and those derived by genetic manipulation. In order to expedite allowance of the instant claims, Applicants have agreed to replace the phrase “Wnt-pathway activator” with “Wnt family member.” Applicants, however, maintain that the specification is enabling for all “Wnt-pathway activators” and reserve their right to pursue such subject matter in one or more continuing applications.

In view of the amendments set forth above, the remarks regarding enablement provided in Applicants response of May 12, 2009 and the remarks made during the telephone interview of September 18, 2009, Applicants respectfully request that the Examiner withdraw the rejection of claims 76-87 under 35 U.S.C. § 112, first paragraph.

35 U.S.C. §102(e)

In the current Office Action, the Examiner maintains the rejection of claims 76, 77, 79, 80 and 82-87 under 35 U.S.C. §102(e) as allegedly anticipated by *Fisk et al.* (U.S. Patent No. 7,326,572) as evidenced by *Kuo et al.*

As discussed in the interview of September 18, 2009 the Examiners indicated that amending independent claim 76 to replace the phrase “Wnt-pathway activator” with the phrase “Wnt family member” would overcome this rejection under 35 U.S.C. §102 because Fisk et al. do not disclose providing a cell population with a TGF $\beta$  superfamily growth factor and a Wnt family member. Although Applicants maintain that Fisk et al. as evidenced by Kuo et al. do not disclose providing a cell population with a TGF $\beta$  superfamily growth factor and a Wnt-pathway

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activator, in order to expedite the allowance of the instant claims, independent claim 76 has been amended to replace the phrase “Wnt-pathway activator” with “Wnt family member.” Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of claims 76, 77, 79, 80 and 82-87 under 35 U.S.C. §102(e).

### **CONCLUSION**

Applicants believe that all outstanding issues in this case have been resolved and that the present claims are in condition for allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is invited to contact the undersigned at the telephone number provided below in order to expedite resolution of such issues.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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